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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/726,883	11/30/2000	Paul E. Harris	62682/JPW/PT	1468

7590

01/28/2004

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EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/726,883

Applicant(s)

HARRIS ET AL.

Examiner

G. R. Ewoldt, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 8-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1-5, and 8-13 are pending and under examination.
2. Applicant's amendment and remarks, filed 11/03/03 are acknowledged. In view of Applicant's amendments and cancellation of Claim 7, the previous rejection under the second paragraph of 35 U.S.C. 112 has been withdrawn. It appears that Applicant's amending of Claim 1 to recite "media for culturing dendritic cells" encompasses the use any media in which DCs might grow, a limitation that is not considered to be indefinite.
3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
4. Claims 1-5, 8-1. and newly added Claim 13, stand/are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record as set forth in Paper No. 7, mailed 7/15/02 and maintained in Papers No. 10 and 16, mailed 12/30/02 and 7/30/03, respectively.

Applicant's arguments, filed 11/03/03, have been fully considered but they are not persuasive. Applicant states, "Applicants have hereinabove amended the claims to place the claims in better form for examination."
"Applicants maintain that the claimed invention as recited in the amended claims is fully enabled by the specification and the specification reasonably conveys to one skilled n the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention."

It appears then that Applicant has not added any new arguments in support of the invention of the instant claims. Accordingly, the rejection is maintained for the reasons of record which are reiterated here.

Step (a) recites the loading of "blood mononuclear cells" into a cell culture container. The specification, however, discloses that it is a "requirement" that the method of the instant claims begin with monocytes and monocyte precursors separated from lymphocytes (page 5, paragraph 4). As such, the method of the instant claims would be highly unpredictable given that the recitation of "blood mononuclear cells" would include lymphocytes in the starting material.

Regarding Step (c) in Claim 1 and Step (d) in Claim 2, and the recitation of "separating nonadherent cells and cells adhered to the beads", Claims 1 and 2 fail to indicate which group of cells is used to generate dendritic cells. As such, the method of the claims must again be considered highly unpredictable because it would appear that the method intends the further culture of one group of cells and the discarding of the other group, but the claims fail to indicate which group is saved and which group is discarded.

Further regarding the incubation of the blood mononuclear cells of the instant claims, the generation of dendritic cells from said blood mononuclear cells would require the inclusion of specific reagents in the incubation, at minimum GM-CSF (in all dendritic cell cultures) and TGF- β (in human dendritic cell cultures, note the intended use of the DCs for the treatment of cancer patients which would encompass human use), see U.S. Patent No. 5,851,756 (column 14, lines 34-35 and Figure 18) and Strobl et al. (1998, Abstract), respectively.

Regarding the method of Claim 12, wherein a ratio has a value sufficient to hold enough media for incubation, the specification fails to disclose what values would be considered sufficient. As recited, the value would encompass a surface area ranging from that of the container alone (no microcarrier beads), to a container packed full of microcarrier beads. It is unclear, however, if either of said values would allow for the reproducible generation of dendritic cells. Thus, the method of the instant claim must be considered highly unpredictable and requiring of undue experimentation.

5. The following are new grounds for rejection necessitated by Applicant's amendment.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, specifically, the claim depends on canceled Claim 7.

8. Claim 13 is rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) "preparing the unprocessed content of the cell culture container," (step b),

B) further recitations of "unprocessed contents",

C) "harvesting the dendritic cell culture from the incubated contents of the cell culture container, including agitating said incubated contents, allowing the beads in the cell culture container to settle after said agitating, and expressing off cell culture suspension into another container," (step e).

Applicant indicates that no new matter has been added but fails to indicate where support for the new limitations can be found in the specification.

9. No claim is allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened

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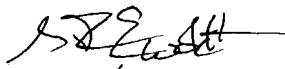
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statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

Please Note: inquiries of a general nature or relating to the status of this application should not be directed to the Examiner but rather should be directed to the Technology Center 1600 Customer Service Center at (703) 308-0198.

G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600


1/22/03
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER